UNCLAS SECTION 01 OF 04 AMMAN 009748

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E.O. 12958: N/A
TAGS: KIPR ETRD KTIA PGOV ECON JO
SUBJECT: JORDAN'S IPR CHALLENGES AND SOLUTIONS: PART III - PHARMACEUTICALS POSE FRONTIER IPR ISSUES

REF: A. AMMAN 9708
¶B. AMMAN 8330 AND PREVIOUS

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THIS IS THE THIRD IN A SERIES OF CABLES ON INTELLECTUAL PROPERTY RIGHTS IN JORDAN. ACTION REQUEST FOR USTR IN PARA 13.

¶1. (SBU) SUMMARY: Protection of original pharmaceutical formulations in Jordan is governed not by patent laws, but by drug registration procedures that allocate exclusive marketing rights for innovative drugs for five years from the date of approval by the Jordan Food and Drug Administration (JFDA). The bilateral Free Trade Agreement (FTA) contains language to protect innovative pharmaceuticals under this registration regime, mainly in the area of data exclusivity and in "unfair competition" provisions. The JFDA is just beginning to confront the IPR issues posed by requests for approvals, and protection, by innovative drug companies. JFDA leadership is committed to Jordanian compliance with international best practices, but notes that these issues are not easily resolved at the international level. At present, unresolved pharma-related IPR issues include affording protection to clinical data regarding different dosages for the same drug submitted at different times; resolving a similar timing problem on data protection between limited government approvals for tenders versus a full market authorization; and protecting rights for "new uses" for previously approved drugs. Beyond IPR, another FTA-related issue is that the JFDA's pharmaco-vigilance regulations may limit initial market access to innovative drugs.

¶2. (SBU) NOTE: The Embassy continues to work with individual U.S. drug companies, as well as the Pharmaceutical Researchers and Manufacturers of America (PhRMA), in pressing the GoJ about its compliance with FTA commitments on pharmaceuticals. After some initial stumbles - including a court case thrown out on a technicality - there is growing recognition within the GoJ that more clarity is required; Minister of Industry and Trade Sharif Zu'bi is working with the JFDA and the Embassy to address these problems, and has underlined that the GoJ will live up to all FTA obligations. END NOTE AND SUMMARY.

First Came the Case of the Weekly Dose

¶3. (SBU) International R&D-based drug firms are comfortable with the registration system in Jordan; to date, Embassy received no complaints of excessive bureaucracy or delayed decisions by the JFDA. Indeed, the JFDA is given good marks by the drug firms for its professionalism and constant efforts at self-improvement. COMMENT: Its multi-agency committees, however, do not have the same reputation, being holdovers from a former paternalistic era of healthcare. END COMMENT. During the first four years of the FTA, IPR protection on clinical trial data for innovative drugs applied to what is called "data exclusivity" by the industry.

¶4. (SBU) When a company filed for protection for a once-a-week-dose drug in 2004 less than a year before the daily dosing would lose its data exclusivity protections (for the clinical data that, once in the public domain, would allow a generic firm to make the same drug and market it at reduced costs), however, pharmaceutical IPR problems ensued. The JFDA did not see why it should protect the separate data set referring to the once-weekly dose; in the eyes of the decision-taking committee, it was the same active chemical ingredient (the "new chemical entity" or NCE) for which the original patent was issued that required protection for one five-year term. Rather than consult or seek a regulatory solution, the JFDA committee at that time was content to see the matter referred to the courts and to abide by a court decision. The court case, however, was dismissed on a

technicality unrelated to the substantive dispute. To the JFDA, the generic company had "won."

¶5. (SBU) In early 2005, a generic company not only produced a daily dose of the contested drug, but also a weekly dose, which incontestably relied on data generated only for the weekly substance and not submitted until 2004. COMMENT: Some in the PhRMA community believe it was a breach of law for the GOJ to fail to uphold the FTA obligation to protect data submitted for the once-weekly dose, regardless of any lower court decision. However, to maintain harmonious relations with its regulator, the aggrieved company - which continues to believe itself to have been wronged - decided not to pursue the case. END COMMENT.

¶6. (SBU) The weekly-dose case raises the general problem with data exclusivity and NCE's in Jordan. For example, an adult dosage, a children's dose, and a pre-school or infant dose - each with its own set of data in support of JFDA approval - should receive, each in its own turn, five years of protection, according to the manufacturer. But the JFDA can't square that proposition with its view of a single NCE deserving only one period of five-year protection. As PhRMA and individual companies read it, the FTA appears to come down more strongly in favor of protections from "unfair competition" and to be more favorable toward data exclusivity in the narrowest sense, for each dose. The main FTA provisions on drugs - FTA Article 4, paragraph 22 and its related footnotes - have yet to be interpreted in a manner acceptable to all, however.

Then Came the non-New-Use "New Uses"

¶7. (SBU) Addressing another drug issue, FTA Article 4, para 22, footnote 10 reads: "...protection for 'new chemical entities' shall also include protection for new uses for old chemical entities for a period of three years." PhRMA companies interpret that to mean that when a drug has a proven new use, it can get an additional three years of data protection, at least for that new use. Just such a drug came along in 2005 - it had been used as an anti-asthma therapy, but new clinical data showed it was also effective for those patients who exhibit both asthma and co-existing allergic rhinitis. NOTE: The U.S. and EU have already approved this new "indication" as a new approved "use". END NOTE

¶8. (SBU) The JFDA ruledthat the drug was approved for the new use, but not for a "new indication." This prompted some in PhRMA to ask, "When is a new use not a new use?" The JFDA argues that the gray area of overlapping uses does not permit a distinction. However, even when innovators are permitted to market a "new use" and to change a patient package insert describing the drug including the "new use" on it, JFDA experts concede that they are not certain this affords every "protection" of the new use for an additional three years. Once the drug's five-year registration expires and a generic becomes available, it is difficult to monitor how doctors prescribe and patients use that generic, versus the original, innovative drug. PhRMA argues that the drug should get full protection for the additional three years, giving it exclusive market access for eight years. The JFDA is studying the issue further. Embassy initially heard that the JFDA was drafting a circular to support the first, ambiguous ruling on the anti-asthmatic. After the innovator appealed, and when Emboffs highlighted the appeal for the JFDA DG, it appears the JFDA will be taking a second, harder look at what "protection" means.

Government Tender Approval vs. Market Authorization

¶9. (SBU) In 2001, an innovating firm's cancer treatment was approved for tender in a government hospital, where most patients in Jordan with the relevant disease are treated. (In these special tender cases, a waiver is obtained from the traditional JFDA approval process.) Soon afterward, the manufacturer filed a formal request for the drug's approval by the national JFDA. This year, an Australian generic of the same drug turned up on the market before five years had elapsed from the JFDA approval. JFDA DG Salah Mawajdeh explained that officials reasoned that the drug had enjoyed five years of data exclusivity, dating from the special tender bid. The manufacturer does not agree, citing the date of the more recent JFDA approval as the time when the clock should have started ticking. JFDA maintains that the same rule applies to all: if a company gets approval under the tender, that's when the data exclusivity clock begins.

Drug Approval Process as Market Access Barrier?

¶10. (SBU) Adding to manufacturers' concerns, the JFDA includes an extra layer of safety to its drug approval

process by requiring that a drug be on the open market in one of seven countries with high safety standards for a full year before it can receive a formal approval in Jordan. As the JFDA speeds up its approval process - it is aiming for 90 working days from submission to approval - that leaves the innovator's drug off the market for at least half a year. PhRMA companies deem this a technical barrier to market access.

¶11. (SBU) For its part, the JFDA argues that clinical trials may be statistically significant, but are still conducted on limited numbers of patients, and cannot equal population-wide use of a drug where rare side effects are seen over the course of a year. The one-year public use monitoring safety requirement is already a compromise on safety concerns, according to the JFDA; some in Jordan would like the period to be as long as five years. A remaining concern for companies is that they might lose access to Jordan's growing, sophisticated medical tourism population during a critical time when a competing drug is already on the market. Firms wonder why - if the drug is the best available - Jordanians should be denied its use when it is already approved in major, safety-conscious countries.

Next Steps: Trade Minister Zu'bi Takes Action
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¶12. (SBU) NOTE: In exchanges with the JFDA and the Ministry of Industry, embassy has emphasized that the GOJ needs to abide scrupulously by its FTA commitments regarding pharmaceuticals. Most recently, we stressed to the JFDA that more bilateral consultation might be in order, given that FTA commitments should be part of Jordan's legal-regulatory framework. The USAID AMIR program has already tasked legal consultants to conduct a gap analysis over the next month to study where relevant legislation might be lacking. Since July, the Embassy has asked the JFDA to consider having the High Committee for Drugs that rules on Directives regarding drug approvals and IPR issues include wider representation of the innovator firms by having a PhRMA representative among three private sector members on the committee. A review of the law that establishes the committee's membership is also needed. Minister of Industry and Trade Sharif Zu'bi took on board in early December Econ/C's suggestion that he consider whether the ministry might join the High Committee, given the growing influence of international trade and trade commitments on the country's overall drugs regime. END NOTE.

¶13. (SBU) On December 8, Minister Zu'bi conducted a meeting with JFDA Director General Mawajdeh to review pharmaceuticals IPR and access issues raised by the FTA. Zu'bi invited Econ/C and Econoff to join the meeting, during which Zu'bi made a firm commitment to reach clear understandings on pharmaceutical IPR protections in line with the FTA. Zu'bi told Econ/C that Jordan wished to be consistent with international best practices and adhere to the FTA. He requested that the USG furnish his ministry with position papers outlining any concerns. Jordan will follow those best practices identified, he said. If any process is not in line with FTA obligations, Jordan will rectify the situation. Zu'bi referred the matter to the JFDA, and offered to help if his further intervention is needed. JFDA's Mawajdeh suggested that the JFDA could speak directly to USG technical experts if that would help resolve FTA-related pharmaceutical matters. He noted that the JFDA has held digital video conferences with U.S. FDA colleagues, and offered to make his team available via this format to any concerned USG agencies. ACTION REQUEST FOR USTR: Please advise on next steps in furnishing requested U.S. position papers on pharma IPR issues to the GOJ.

¶14. (SBU) COMMENT: Over the past 18 months, circumstances have created a critical mass of test cases related to the FTA-mandated data exclusivity and "unfair competition" protections. Taken together, these issues now command high-level attention in the Ministries of Trade and Health, and in the JFDA. Embassy will follow up on developments over the next months in the run-up to the FTA Joint Committee. END COMMENT.

¶15. (U) Next installment on IPR: Enforcement.

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